

Decision Memo for Autologous Stem Cell Transplantation (AuSCT) for Multiple Myeloma (CAG-00011R)

Decision Summary

After careful reconsideration, HCFA has concluded that it will remove the age requirement in its national coverage policy on AuSCT for patients with multiple myeloma. This conclusion was reached based on the following findings:

- Age did not appear to be an independent predictor of outcome for multiple myeloma patients undergoing AuSCT in several multivariate models.^{1, 2, 3}
- Based on studies of reasonable quality, elder multiple myeloma patients do have superior outcomes when undergoing high-dose chemotherapy followed by AuSCT compared to standard-dose chemotherapy.
- Although the available evidence on whether patients under age 60 benefit more than patients over age 60 is equivocal, it appears that there is not a strong age effect in terms of benefit from this treatment (most likely due to the fact that older patients selected for transplant are otherwise healthy older patients).
- There is no clear evidence that multiple myeloma patients over age 75 who underwent AuSCT have worse outcomes compared to younger patients.
- HCFA has stated in its national coverage policy that the procedure will only be covered in patients that have adequate renal, hepatic, pulmonary, and cardiac function. This requirement should identify older patients with significant comorbidities who might not benefit from treatment.
- The decision about how old is too old will also be left to the treating physician. This is consistent with HCFA's policy on not having specific cutoff points for creatinine clearance and hepatic, pulmonary, and cardiac function.

The coverage instructions in the *Coverage Issues Manual* will be modified accordingly.

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Decision Memo

TO: Administrative File: CAG-00011B
Autologous Stem Cell Transplantation (AuSCT) for Multiple Myeloma

FROM:

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SUBJECT: National Coverage Decision

DATE: February 9, 2001

In August 1999, The Health Care Financing Administration (HCFA) internally generated a request for the coverage of autologous stem cell transplantation (AuSCT) in patients with multiple myeloma (see CAG-00011A). During the course of this coverage review, HCFA examined the available evidence and referred the issue to both the Medicare Coverage Advisory Committee and to Blue Cross Blue Shield Technology Evaluation Center for a technology assessment. After careful review of all available information on the topic, HCFA issued a national coverage determination for single AuSCT in patients with Durie-Salmon stage II or III patients that fit the following requirements:

1. Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease *either* in measurable paraprotein [serum and/or urine] *or* in bone marrow infiltration, sustained for at least one month), and those in responsive relapse;
2. Adequate cardiac, renal, pulmonary, and hepatic function; and
3. Age < 77 years.

Due to insufficient evidence, tandem transplantation for multiple myeloma remained non-covered. This policy became effective for services rendered on or after October 1, 2000.

The primary basis for an age cut-off was that no patient over age 77 had been enrolled in any reported trial of this therapy. It was felt that this probably indicated that clinical investigators found most, if not all, patients over 77 to be poor candidates for this treatment, possibly due to co-morbidity.

On November 23, 2000, HCFA internally-generated a formal coverage request to reexamine the issue of age as a predictor of treatment outcome and whether it is an appropriate limitation in Medicare's coverage policy on AuSCT for patients with multiple myeloma. The agency invited interested parties to submit relevant information regarding this topic. No new information was submitted to the agency. Staff in the Coverage and Analysis Group reexamined the evidence from the previous coverage review on AuSCT for patients with multiple myeloma.

After careful reconsideration, HCFA has concluded that it will remove the age requirement in its national coverage policy on AuSCT for patients with multiple myeloma. This conclusion was reached based on the following findings:

- Age did not appear to be an independent predictor of outcome for multiple myeloma patients undergoing AuSCT in several multivariate models. [1](#), [2](#), [3](#)
- Based on studies of reasonable quality, elder multiple myeloma patients do have superior outcomes when undergoing high-dose chemotherapy followed by AuSCT compared to standard-dose chemotherapy.

- Although the available evidence on whether patients under age 60 benefit more than patients over age 60 is equivocal, it appears that there is not a strong age effect in terms of benefit from this treatment (most likely due to the fact that older patients selected for transplant are otherwise healthy older patients).
- There is no clear evidence that multiple myeloma patients over age 75 who underwent AuSCT have worse outcomes compared to younger patients.
- HCFA has stated in its national coverage policy that the procedure will only be covered in patients that have adequate renal, hepatic, pulmonary, and cardiac function. This requirement should identify older patients with significant comorbidities who might not benefit from treatment.
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The coverage instructions in the *Coverage Issues Manual* will be modified accordingly.

¹ Siegel D, et al. 1999.

² Palumbo A, et al. 1999.

³ Vesole D, et al. 1999.

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